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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,438	01/10/2006	Takahiro Hara	09859/0203826-US0	8952
7278	7590	05/12/2009		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER TRAN, SUSAN T	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 05/12/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/564,438

Applicant(s)

HARA ET AL.

Examiner

S. Tran

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/55/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faham et al. US 6,723,348, in view of Rasmussen US 5,977,158 or Furitsu et al. US 6,743,443.

Faham teaches a orodispersible tablet containing active agent, and a mixture of excipient comprising disintegrant, soluble diluent, sweetening agent, flavoring agent, and optionally a swelling agent and a permeabilizing agent (abstract; column 4, lines 1-38; and claim 1). Soluble diluent includes mannitol, xylitol, microcrystalline cellulose, lactose, starches, dicalcium phosphate, sucrose, sorbitol, maltitol, and mixture thereof (column 4, lines 42-47). Amount of soluble diluent is from 30-90% (claim 9, column 3, lines 35-41; and column 8, lines 1-10). Faham also teaches a process for preparing the orodispersible tablet, and the use of lubricant on the surface of the tablet, wherein the lubricant is sprayed on the surface of the punches before tableting (column 6, lines 59 through column 7, lines 1-16). The tablet has a disintegrating time of less than 40 seconds, and a hardness of 45 N (Table 10).

Faham does not expressly teach soluble diluent such as cyclodextrin.

Rasmussen teaches a tablet formulation comprising water-soluble diluent such as lactose, sucrose, dextrose, mannitol, xylitol, sorbitol, and cyclodextrins (column 4, lines 10-15).

Furitsu teaches a tablet composition comprising filler such as crystalline cellulose, dextrin, and various kind of cyclodextrin including α -cyclodextrin, β -cyclodextrin, and γ -cyclodextrin (column 12, lines 46-49).

Thus, it would have been obvious to one of ordinary skill in the art to optimize the orodispersible tablet of Faham to include the use of cyclodextrin as a tablet diluent to obtain the claimed invention. This is because Rasmussen teaches the equivalency between mannitol and cyclodextrin as a water soluble diluent, because Furitsu teaches the use of cyclodextrin as a filler in an oral dispersible tablet is known in the art, because Furitsu teaches the equivalency of microcrystalline cellulose and cyclodextrin as a tablet filler/diluent, and because Faham teaches the use of diluent such as mannitol or microcrystalline cellulose in the claimed amount, e.g., up to 90% (claim 9).

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cappola et al. is cited as of interest for the teachings of tablet composition comprising more than about 10% betacyclodextrin. Loftsson is cited for the teachings of cyclodextrin/drug complexation.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615